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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|-------------------------|------------------------|
| 10/733,686 | 12/10/2003 | Yaron Ilan | 59046.000043 | 9035 |
| 21967 7590 01/28/2009 HUNTON & WILLIAMS LLP INTELLECTUAL PROPERTY DEPARTMENT 1900 K STREET, N.W. SUITE 1200 WASHINGTON, DC 20006-1109 | | | EXAMINER LE, EMILY M | |
| | | | ART UNIT 1648 | PAPER NUMBER |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

**Advisory Action
Before the Filing of an Appeal Brief**

Application No.

10/733,686

Applicant(s)

ILAN ET AL.

Examiner

EMILY M. LE

Art Unit

1648

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 17 December 2008 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: _____.
Claim(s) objected to: _____.
Claim(s) rejected: _____.
Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____.
13. ☐ Other: _____.

/EMILY M LE/
Primary Examiner, Art Unit 1648

Continuation of 11, does NOT place the application in condition for allowance because: The claims remain rejected for reason(s) set forth in the record.

In the 12/17/2008 filing, Applicant asserts that the claimed invention is enabling. Applicant argues that Applicant has clearly taught the administration of glycolipids for the treatment of HCV infection.

This argument has been considered, however, it is not found persuasive. Contrary to Applicant's argument, Applicant has not clearly taught the administration of glycolipids for the treatment of HCV infection. Nothing exists in the specification to evidence that Applicant has clearly taught such.

Applicant also asserts that the Office appears to have equated "treatment" with "cure".

Applicant's assertion has been noted, however, the assertion is incorrect. Had the Office intended treatment with cure, the Office would have clearly stated such in the office action.

The disease being treated has been noted to not encompass all disease, however, it remains that the elected invention and the invention under examination is directed to a method of treating HCV.

Applicant asserts that the Office may not read limitations, such as mechanism of actions, into the claims that are not part of the claim.

Applicant's assertion has been considered, however, it is not found persuasive. Claims are given its broadest and reasonable interpretation. In the instant case, contrary to Applicant's assertion, the Office does not interpret the mechanism of action as a limitation of the claims. Rather, mechanism of actions is inherent of the product or the process.

Applicant additionally cites several arts to demonstrate that treatment of HCV may be performed despite the problems cited by the Office. The arts and argument have been considered, however, it is not persuasive. The issue is not whether treatment of HCV may be performed despite the problems/challenges encounter in the HCV art. Rather it is whether the skilled artisan would be able to practice the claimed invention without undue experimentation. In the instant case, in view of the lack of enablement analysis, it is found that the skilled artisan would not be able to practice the claimed invention without undue experimentation.

Applicant further argues that the only experimentation involved is routine experimentation, such as establishing the route of administration and treatment dosage amounts. Applicant's argument has been considered, however, it is not found persuasive. As established in the Office action, the undue experimentation imposed upon the skilled artisan attempting to practice the claimed invention is beyond routine experimentation. In the instant case, Applicant has failed to demonstrate that glycolipids treat HCV.